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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,672	01/22/2002	Michael Fonseca	501032.20502 (24301.11)	5258

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REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 12/30/2003

121

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,672

Applicant(s)

FONSECA ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15, 16, 22, 23 and 25-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-31 and 55-59 is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 15, 16, 22, 23, 25-27, 32-41, 44, 47-53 and 60-64 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 28, 42, 43, 45, 46 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 2, 35, 60 and 61 are objected to because of the following informalities: regarding claim 2 and claims with similar limitations, it would appear to be more accurate to state that the *capacitance* of the capacitor is variable rather than stating that the capacitor itself is variable; the reference to the upper inductor coil and the lower conductor coil in claim 60 lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 11, 15, 16, 22, 23, 25-27, 32-38, 44, 47-53 and 60-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Gershenfeld et al. (Pat. No. 6,025,725).

Regarding claims 1, 32 and 33, Gershenfeld et al. disclose a sensor comprising a self-contained resonant circuit comprising a capacitor and an inductor to form an LC resonator, wherein the circuit is variable in response to the physical property of a patient (note in particular col. 2, lines 6-18 and lines 48-59 as well as col. 3, lines 25-31). The intended use of determining a physical property in a patient's heart chamber was considered, but deemed insufficient to saliently distinguish over the sensor of Gershenfeld et al., which, if placed in a heart chamber, would be capable of sensing a physical property of said chamber.

Concerning the recitation regarding the sensor's flexibility, the examiner considers the sensor of Gershenfeld et al. to be sufficiently flexible to be folded for delivery percutaneously. The applicants are not claiming the sensor to be folded, but simply that the sensor be sufficiently flexible *to be* folded. Gershenfeld et al. teach that it is desirable to manufacture relatively thin flexible sensors (note col. 1, lines 49-66, and in particular col. 8, lines 11-14). They further refer to suitable dielectric materials for use in the construction of the invention, including among the list polyvinylidene difluoride

(PVDF) in sheet form (col. 2, lines 18-31). The polymer PVDF in sheet form is known by those of ordinary skill in the material sciences to be flexible and easily shapeable. Gershendfeld et al. additionally show the substrate of the sensor to be folded onto itself (see Fig. 4) lending further credence to its flexibility.

Regarding claim 5 and claims with similar limitations, the examiner considers the measurement of applied force to be equivalent to the measurement of pressure.

Regarding claims 11, 16 and 27, the applicants are not claiming the sensor to comprise a folded shape of the type set forth, but simply that the sensor shape can be folded in such a manner. By analogy, a rectangular sheet of paper is capable of being folded into a wide variety of shapes, but the fact that something can be folded into said shapes does not necessarily mean that it is.

Concerning claims 15 and 47, note col. 7, lines 10-13. The functional language "...to facilitate folding..." was considered by the examiner to constitute merely a recitation of desired result.

Regarding claim 23, the examiner directs the applicants' attention to col. 7, lines 22-26.

In regards to claim 25, note col. 8, lines 14-17.

Concerning claim 26, the examiner considers the stacked construction shown in Fig. 6 to constitute a capacitance distributed across an array of smaller capacitances.

Regarding claim 34, the examiner considers the embodiment discussed by Gershenfeld et al. comprising a sensor embedded in a bandage (col. 3, lines 25-31) to constitute a sensor with an anchoring system (i.e., the bandage). Since the sensor of Gershenfeld et al. is essentially a thin planar sheet having two flat surfaces, the examiner considers any such sensor embedded in a bandage to be a sensor with an anchoring system attached to a flat surface thereof.

Concerning claim 60, Gershenfeld et al. disclose a sensor comprising two spiral coils of opposite helicities on a single sheet that may be folded as shown for example in Fig. 4. The upper and lower coils are connected without via holes or additional conductive connections as seen in Fig. 4.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-8 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershenfeld et al. (Pat. No. 6,025,725).

Although Gershenfeld et al. do not disclose the use of a sensor with a disk shape, it is taught that the resonator can be "...constructed in a variety of configurations, depending on the application, the desired output signal strength, the location of the resonant frequency, etc...." (col. 5, lines 37-40). To employ a disk shape as opposed to a rectangular shape would have therefore been considered a matter of obvious design by those of ordinary skill in the art.

Allowable Subject Matter

6. Claims 29-31 and 55-59 are allowed.

In regards to claim 29, the prior art of record does not disclose a sensor delivery system comprising the recited sensor in combination with the recited catheter and inner cylindrical member.

Referring to claim 55, the prior art of record does not disclose a teaching or suggestion for modifying the art of record to include the recited safety wire.

7. Claims 9, 10, 28, 42, 43, 45, 46 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 9 and 42, there does not appear to be a suggestion or teaching in the prior art of record for incorporating a metallic ring surrounding a portion of the edge of the sensor. Such a ring as disclosed is preferably radio opaque to locate the sensor in the body.

Regarding claims 10, 28, 43 and 54 there is no teaching in the prior art of record for incorporating a daisy or flower shape as defined in the specification into the sensor of Gershenfeld et al.. Applicants state that such a shape allows for easier insertion into a catheter for implant into the body.

Concerning claims 45 and 46, there is no teaching in the prior art of record for modifying the sensor of Gershenfeld et al. to include either a coil anchor or an anchor with umbrella-like radial projections.

Response to Arguments

8. Applicant's arguments filed September 30, 2003 have been fully considered but they are not persuasive.

The applicant argues that Gershenfeld et al. only disclose a sensor having a flexible membrane layer, with no disclosure that the entire sensor is flexible or capable of being folded for percutaneous delivery. The examiner again refers the applicant to col. 8, lines 11-14 wherein it is stated, "...the LC resonator *package* [emphasis added] can be made to be very thin and flexible...." The term "package" refers not just to the membrane material as the applicants appear to infer, but to the entire sensor. The applicants should also note Fig. 4 and col. 5, lines 36-49 wherein it is disclosed that the sensor can be folded onto itself. Conclusory statements by the applicants that the sensor is not flexible or capable of percutaneous delivery will be insufficient to overcome the rejection under 35 U.S.C. §102.

The applicants also argue that there is no suggestion in Gershenfeld et al. of a method or system of introduction into a patient's body, nor is there a discussion of the use of materials or coatings that are safe and practical for intra-body applications. The present claims, however, do not disclose a method or system of introduction into a patient's body –merely a sensor with the intended use of determining a physical property in a patient's heart chamber, and that is sufficiently flexible to be folded for percutaneous delivery. Regarding the use of coatings, the examiner can find no limitation in claims 1, 32 or 33 regarding the use of such materials. Limitations appearing in the specification but not the claims may not be read into the claims (*In re*

Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969)). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Information Disclosure Statement

9. The IDS received October 2, 2003 was not accompanied by copies of the listed references. The examiner requests that the applicants submit copies of the foreign patent documents and non-patent literature so that these documents may be considered.

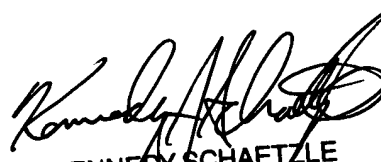
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
December 28, 2003


KENNEDY SCHAETZLE
PRIMARY EXAMINER